REC'D 13 SEP 2005
WIPO PCT

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference WN/MSR/XA.11	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/GB2004/002522	International filing date *(day/month/year)* 14.06.2004	Priority date *(day/month/year)* 14.06.2003
International Patent Classification (IPC) or national classification and IPC A61N1/39		
Applicant MILLS, Desmond Bryan ET AL.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 1 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand 14.01.2005	Date of completion of this report 14.09.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Ferrigno, A Telephone No. +31 70 340-2174

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2004/002522

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages	
1-16	as originally filed
Claims, Numbers	
5-32	as originally filed
1-4	received on 21.02.2005 with letter of 21.02.2005
Drawings, Sheets	
1/5-5/5	as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2004/002522

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	7-29, 31,32
	No:	Claims	1-6,28
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-32
Industrial applicability (IA)	Yes:	Claims	1-32
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:
D1 : US-A-6 073 085
D2 : US-A-5 810 771
D3 : EP-A-1 002 555
D4 : US-A-5 812 397
D5: US-A-5 899 925
D6: US-A-5 879 374

The documents D5 and D6 were not cited in the international search report.

1) Preliminary Observations:

The amendments filed with the letter dated 21. 02. 2005 introduces subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendments concerned are the following.

Amended claim 1 recites that "each of the self-test means initiates its self-test routine autonomously".

This statement has not been originally disclosed as such.

Furthermore, amended claim 1 does not contain the original feature that "the self test being activated independently of operation of the medical device and not by a signal from a processor associated with said medical device"

Prima facie the two statements are equivalent. This is however not the case, since it is not clear whether or not the amended feature ("each of the self-test means initiates its self-test routine autonomously") requires that each of the self-test means initiates its self-test routine without any activation by other means.

If the amended feature has to be merely interpreted that the self-test means initiates its self-test routine independently from each other and that therefore other means (cf. claims 15-18, and 31) can activate the self-test routine, then the subject-matter of amended claim 1 is also directed to a device wherein the self-test means initiates its self-test routine independently from each other but they are controlled by signals "from a processor associated with said medical device".

This possibility was not originally disclosed.

Furthermore, since amended claim 1 does not contain the original feature that "said medical device being arranged to send information concerning components of said medical device to an indicator which can show the status of the components when tested", the subject-matter of amended claim 1 is also directed to devices taking actions other than displaying information and there is therefore a broadening of the claim not supported by the original disclosure.

2) Furthermore, the above-mentioned addition of new subject-matter notwithstanding, the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT, and therefore the criteria of Article 33(1) PCT are not met.

D5 discloses a self test system for a medical device comprising a plurality of components.

"Each of the various tested defibrillator components may itself contain circuitry (not shown) for testing and communicating component status to the CPU 16 and system monitor 12" (cf. col. 3, lines 60-63).

"The testing circuit can also be conveniently powered separately from other components of the AED 10, resulting in energy savings. The system monitor 12 can then include its own separately dedicated power supply (not shown), which may be powered by the main battery 14 or by a separate dedicated battery (not shown)" (cf. col. 4, lines 13-19).

Hence, D5 discloses a system wherein each component has independent self-testing means that can initiate self-test routines independently from each other: the disclosed

system falling therefore within the wording of claim 1.

It should be noted that the question whether or not all test routines are initiated centrally by the monitor 12 is irrelevant, since amended claim 1 includes (see paragraph 1 above) this possibility.

However, although document D5 discloses (col. 3, lines 47-49) that the "system monitor 12 generates test signals at various times and in response to specified events, such as power-on events, to initiate testing of defibrillator functions", this is just one of the possible embodiments.

In a further embodiment D5 discloses that each "of the various tested defibrillator components may itself contain circuitry (not shown) for testing and communicating component status to the CPU 16 and system monitor 12. For example, the ECG circuit 24 may include a signal generator for generating test ECG signals to test ECG amplifier and analog-to-digital converter functions, etc.". In this further embodiment therefore the test routines are initiated by the signal generators of testing units and not centrally by the monitor 12 .

Furthermore, document D6 also discloses a system which falls within the wording of claim 1 (cf. col. 3, lines 26-50, col. 5, lines 4-9).

3) Since both D5 and D6 disclose systems that are powered independently from the CPU, also the subject-matter of claim 2 is not new.

4) Furthermore, D6 discloses defibrillator status indicator 28 and that "the result of each self-test in each group affects the status is indicated on status indicator 28. This collection of self-testing subsystems may be added to or subtracted from". Hence, although not disclosed explicitly, the device comprises a summator to add the result of self-testing subsystems. Hence, in one embodiment the status indicator 28 acts as a summator and therefore the subject-matter of claims 3 and 4 is not new.

5) The features of apparatus claims 5 and 6 and method claim 30 are also disclosed in D5 and D6 and therefore the subject-matter of these claims is not new.

6) The additional features of claims 7-29, 31 and 32 are just some of several straightforward possibilities (cf. D1-D4) from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill. Hence, the subject-matter of these claims does not involve an inventive step in the sense of Article 33(3) PCT and therefore the application does not meet the criteria of Article 33(1) PCT.

Claims

1. A self test system for a medical device comprising a plurality of components each of which has a respective self-test means associated therewith capable of carrying out a self-test routine on the associated component, wherein each of said self-test means initiates its self-test routine autonomously with the results thereof being passed to a common processor.

2. A self test system for a medical device according to claim 1, wherein the self test is activated independently of operation of the medical device and not by a signal from the centralized processor associated with said medical device.

3. A self test system for a medical device according to claim 1 or claim 2, wherein the self test system includes a summator which receives data from the one or more self test units about said components, the summator storing said data so that it can be transmitted to an indicator either directly or via a processor which can access said data.

4. A self test system for a medical device said medical device being arranged to transmit information concerning components of said medical device to an indicator which can show the status of the components when tested, characterised in that the self test system comprises one or more self test units which can self test one or more individual components of the medical device and a summator which receives data from the one or more self test units about said components, the summator storing said data so that it can be transmitted to an indicator either directly or via a processor which can access said data.